REMARKS/ARGUMENTS

I. THE STATUS OF THE CLAIMS

Claims 1-6, 8-19, and 21-25 are pending. Claims 1-17, 19, 21 and 22 stand rejected and claim 18 currently stands withdrawn. Claim 7 has been cancelled without prejudice, claims 1, 19, and 22 have been amended without prejudice to recite the inclusion of polyvinylpyrrolidone, and new claims 23-25 have been added. Applicants reserve the right to pursue the original scope of claims 1, 19, and 22 in continuation/divisional applications. Support for such amendments can be found throughout the specification, including original claim 7 and 22. Accordingly, no issues of new matter are believed to be raised by the above amendments to the claims.

II. THE REJECTION UNDER 35 U.S.C. § 103

Claims 1-17, 19, 21-22 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gowan, Jr. (US 5374659 A-previously presented), Gergely et al. (US 5,834,019 A-previously presented), Patel et al. (US Pat No. 6,569,463), Eichman (US Pat. No. 5,980,882-previously presented), and Hagemann et al. (US Pat. 5,211,957). See Pages 2-8 of the Office Action. Applicants again respectfully disagree.

As previously asserted by Applicants, none of the cited references, alone or in combination, disclose or suggest the claimed invention. The claimed invention is a pharmaceutical aqueous suspension comprising a therapeutically effective amount of suspended solid particles in crystal form and polyvinylpyrrolidone, wherein the suspension has a pH of about 3.7 to about 8.

While Gowan, Jr. discloses an aqueous pharmaceutical suspension containing a water-insoluble pharmaceutical active and xanthan gum, as recognized in the final Office Action, "[t]he reference fails to teach the active agent, loratadine, the nucleation inhibitor, PVP, and the amino polycarboxylic acid, EDTA." See Page 3 of the Office Action.

As acknowledged in the Office Action, Gergely merely discloses inherent properties of loratadine, including that it is water-insoluble and that it has a strong hydrophobic character (see col. 1, lines 22-33 and Office Action at page 3). Gergely does not teach, or suggest, the use of loratadine in an aqueous suspension. In fact, it actually teaches away by teaching the use of loratadine in a effervescent tablet. Accordingly, one of ordinary skill in the art would not look to

combine the teachings of Gergely and Gowan, Jr. to arrive at the aqueous suspension of the present invention.

As with Gergely, Patel also relates to solid dosage forms. Accordingly, one of ordinary skill in the art would not look to combine the teachings of Gergely and Gowan, Jr. to arrive a the aqueous suspension of the present invention.

Eichman discloses pharmaceutical compositions comprising a drug-resin complex and a chelating agent in which the composition is in the form of a solid or a gel. While, Eichman discloses that EDTA is known to stabilize drugs in solution by retarding their oxidation. See col. 2, lines 60-61, Eichman does not disclose Eichman discloses that the drugs disclosed therein are not in solution. See col. 3, lines 57-61. Like Gowan, Gergely and Patel, Eichman does not disclose or suggest a combination of elements that achieves the features recited in the claims.

Furthermore, in the interests of furthering this application to allowance, as discussed above, Applicants have amended independent claims 1, 19, and 22 to now include polyvinylpyrrolidone ("PVP"). Applicants submit herewith the Declaration Under 37 CFR 1.132 of Gail Buehler ("Buehler Declaration"). As set forth in the Buehler Declaration, four suspensions of loratadine were compared- namely, one without PVP, one with 1.5% PVP, one with 2.5% PVP, and one with 5% PVP. As recited in the Buehler Declaration, it was surprisingly discovered that the suspensions containing 2.5% and 5% PVP "showed no elongated crystal needles of loratadine, demonstrating the inhibition of crystal growth upon storage. Crystalline growth of the active agent is not preferred in suspensions because of the potential formation of inactive polymorphs of the active and the possible loss of bioavailability of the active agent because of the growth in size of the crystals." None of the four references teach, or suggest, that PVP would inhibit the crystalline growth of an active ingredient in suspension.

Accordingly, reconsideration and withdrawal of the rejection of claims 1-17 and 19-22 under 35 U.S.C. § 103 as being obvious over Gowan, Gergely, Patel and Eichman are respectfully requested.

III. CONCLUSION

Early consideration and prompt allowance of the claims are respectfully requested. Should the Office require anything further, it is invited to contact Applicants' representative at the telephone number below.

Respectfully submitted,

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